APPENDIX A

Statutes

28 U.S.C. § 1254. Court of appeals; certiorari; appeal; certified questions

"Cases in the courts of appeals may be reviewed by the Supreme Court by the following methods:

"(1) By writ of certiorari granted upon the petition of any party to any civil or criminal case, before or after rendition of judgment or decree; . . ."

28 U.S.C. § 1331. Federal question; amount in controversy; costs

"(a) The district courts shall have original jurisdiction of all civil actions wherein the matter in controversy exceeds the sum or value of $10,000, exclusive of interest and costs, and arises under the Constitution, laws, or treaties of the United States."

28 U.S.C. § 1337. Commerce and anti-trust regulations

"The district courts shall have original jurisdiction of any civil action or proceeding arising under any Act of Congress regulating commerce or protecting trade and commerce against restraints and monopolies."

28 U.S.C. § 2201. Creation of remedy

"In a case of actual controversy within its jurisdiction, except with respect to Federal taxes, any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought. Any such declaration shall have the force and effect of a final judgment or decree and shall be reviewable as such."

APPENDIX B

Opinion of the United States District Court for the Southern District of New York

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

67 Civ. 2115

AMP INCORPORATED, *Plaintiff*,

v.

JOHN W. GARDNER, Secretary of Health, Education and Welfare; and JAMES L. GODDARD, Commissioner of Food and Drugs, *Defendants*.

TENNEY, *J.*

The principal question presented to the Court in this declaratory judgment action is whether certain items manufactured by plaintiff are "drugs" or "devices" within the meaning of the Federal Food, Drug;[,] and Cosmetic Act, 52 Stat. 1040 (1938), 21 U.S.C. §§ 301-392 (1964). Plaintiff manufacturer and defendants, the Secretary of Health, Education and Welfare, and the Commissioner of Food and Drugs, have each moved for summary judgment, plaintiff claiming the items are "devices" and the defendants claiming they are "drugs". Both parties agree that there are no facts in issue. The Court is of the opinion that the items are properly characterized as drugs and, accordingly, plaintiff's motion for summary judgment will be denied and the defendants' cross-motion for summary judgment will be granted.

The products in issue are items used by surgeons for ligating or tying bleeding vessels during surgical procedures on the human body. The products consist of (a) a disposal instrument in the form of either a hemostat (clamp) or a long slender tube which is used to locate

bleeders and apply a nylon ligature loop and a nylon lock in the shape of a minute button, (b) the nylon ligature loop, and (c) the nylon lock. The ligature consists of a length of filamentary material having a loop at one end for encircling a blood vessel. The "button" serves the function of a knot for maintaining the ligature loop in a tightened position. Under ordinary surgical procedures, a surgeon will tie off all severed vessels by a hand-tied surgeon's knot which is a reef knot.

Plaintiff claims that its products are mechanical instruments, that the nylon ligature loop and the locking device are merely components, parts or accessories thereof, and that therefore the whole product is a device. Defendants argue that plaintiff's hemostat and long slender tube constitute a new and unique method of administering or applying a nylon suture, that a suture is a "drug" within the meaning of the statute and that since such method "is not generally recognized among experts . . . as safe and effective for use under the conditions . . . recommended" by the manufacturer, it is a new drug under § 201(p) of the Act, 21 U.S.C. § 321(p) and 21 C.F.R. § 130.1(h)(5).

To a great extent, there is no difference between the treatment accorded products characterized as "drugs" and those denominated as "devices" under the Act. For example, the adulteration or misbranding of any drug or device is prohibited under sections 301, 501 and 502 of the Act, 21 U.S.C. §§ 331, 351, 352. The same sanctions (injunction, criminal prosecution and seizure) may be invoked as to both drugs and devices pursuant to sections 302, 303, 304 of the Act, 21 U.S.C. §§ 332, 333, 334. However, a critical difference arises in that section 505 of the Act, 21 U.S.C. § 355, provides that no person shall introduce into interstate commerce a new drug unless an application with respect to the drug has been approved by the Secretary of Health, Education and Welfare. Prior to marketing a new drug commercially, an applicant must show that his product will be safe and effective for its intended use. There

is no pre-market clearance requirement for devices; after distribution of the device, the Government has the burden of proving that the particular item is misbranded.

On January 19, 1966, plaintiff wrote to the Food and Drug Administration requesting classification of its products as drugs, new drugs or devices. (Complt. Exh. C.) By letter dated March 18, 1966, plaintiff was advised that the products were regarded as new drugs. (Complt. Exh. D.) On May 4, 1966, plaintiff filed a "Notice of Claimed Investigational Exemptions", IND No. 3283, pursuant to § 505(i) of the Act, 21 U.S.C. § 355(i).

On November 9, 1966, Dr. William J. Gyarfas, Acting Director of Dental and Surgical Adjuncts of the Food and Drug Administration, met with representatives of plaintiff to discuss the status of IND No. 3283. Plaintiff was advised of various deficiencies and was told that long-term studies concerning the possible cancer-producing effects of the nylon filament and button would be required. (Gyarfas affidavit at ¶ 12.) Plaintiff subsequently decided that its products were devices rather than new drugs and on January 6, 1967, defendants were informed that plaintiff was withdrawing IND No. 3283 for that reason. (Complt. Exh. E.)

Plaintiff proceeded to comply with the requirements of the Act relating to devices, and on January 31, 1967, a sample label was sent to the Division of Medical Devices of the Food and Drug Administration. (Complt. Exh. F.) On February 17, 1967, plaintiff was advised of suggested changes in the labeling of the products.[1] However, in a

[1] Plaintiff contends that this letter of the Food and Drug Administration constituted "tacit approval" of the characterization of the products as devices (Plaintiff's Statement Under Rule 9(g), ¶ 4), and that plaintiff relied on such statement in marketing the products. The instant complaint does not ask that damages be awarded. In any event, the principle of estoppel cannot be asserted against the Government so that withdrawal of this "tacit

subsequent letter to plaintiff from Dr. Gyarfas on April 26, 1967, plaintiff was again advised that the products were considered drugs and that failure to comply with investigational drug regulations might result in the commencement of regulatory proceedings. Finally, on May 1, 1967, defendants' telegram recalled the February 17, 1967 letter concerning labeling.

In response to defendants' threats of initiation of regulatory action, the products were taken out of interstate commerce and the instant action was commenced. The complaint seeks a declaratory judgment declaring plaintiff's products to be devices and an injunction against enforcement of the "drug" and/or "new drug" provisions of the Act against plaintiff or its ligating products.

Jurisdiction of this action is based on 28 U.S.C. §§ 1331 (a), 1337. Defendants concede that the declaratory judgment procedure is a proper one to challenge a final determination of the Commissioner of Food and Drugs. See *Abbott Labs.* v. *Gardner*, 387 U.S. 136 (1967); *Gardner* v. *Toilet Goods Ass'n*, 387 U.S. 167 (1967); *Toilet Goods Ass'n* v. *Gardner*, 387 U.S. 158 (1967).

Determination of the Essential Element of Plaintiff's Products

As has been hereinbefore stated, plaintiff contends that the nylon loop and the locking device are merely components of the mechanical instruments. Defendants argue that plaintiff's products are actually sutures with the instruments merely being a new method of applying such sutures.

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approval" will not be actionable. *Legerlotz* v. *Rogers*, 266 F. 2d 457, 458 n. 5 (D.C. Cir. 1959), cert. dismissed, 362 U.S. 938 (1960); *United States* v. *Ohio Oil Co.*, 163 F. 2d 633, 641 (10th Cir. 1947), cert. denied, 333 U.S. 833 (1948); *United States* v. *Glens Falls Indem. Co.*, 152 F. Supp. 840 (S.D.N.Y. 1957); see *Utah Power & Light Co.* v. *United States*, 243 U.S. 389, 409 (1917).

The Court is of the opinion that the hemostat or the tube is no more than a container for and method of applying the suture. It is the suture which does the work of tying off the blood vessels and it is the suture which remains in the body. If the suture were physically separate from the mechanical apparatus, this would not result in a loss of suturing effect but would merely alter the manner of administration of the suture.

If the suture itself is considered a drug for the purposes of the Act (the conclusion reached herein), then plaintiff's products are comparable to drugs administered by disposable syringes. The syringe alone is a device when used separately. 1 Toulmin, Foods, Drugs & Cosmetics § 4.13, at 54 n.2, § 4.33, at 79 (2d ed. 1963). But a drug in a syringe will not become a component of a device or a device for purposes of the Act simply because it is packed for use in such a syringe.

Accordingly, it is the opinion of this Court that the essential element of plaintiff's products is the suture.

Classification of the Suture as a Drug or Device

Section 201(g) of the Act, as amended, 21 U.S.C. § 321(g) defines "drug" as

> (A) articles recognized in the official United States Pharmacopeia . . . and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease . . . and (C) articles (other than food) intended to affect the structure or any function of the body . . . and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C) of this paragraph; but does not include devices or their components, parts, or accessories.

Similarly, section 201(h) of the Act, 21 U.S.C. § 321(h) defines "device" as

> instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease . . . or (2) to affect the structure of any function of the body. . . .

It is apparent from the above definitions that the "drug" and "device" definitions contain overlapping elements. Thus, a drug and device are both defined, in part, as items intended "for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" and as items intended "to affect the structure or function of the body." However, the drug includes "articles recognized in the official United States Pharmacopeia. . . ." Additionally, the entire definition of a "drug" is qualified by the statement that it "does not include devices or their components, parts, or accessories." For this reason, both parties argue that the terms are mutually exclusive and an item considered a drug under the Act cannot be a device. Brief for Plaintiff, p. 8; Defendants' Reply to Plaintiff's Statement Under Rule 9(g), ¶ 2. However, "the categories . . . 'drug' and 'device' should not be defined as mutually exclusive." 1 Toulmin, *op. cit. supra* at § 4.15.

The major differences thus appear to be the requirement that a "drug" be listed in an official compendium and the characterization of a "drug" as an "article" and a "device" as an "instrument", "apparatus" or "contrivance". The Act does not define these terms and, consequently, it is necessary to consider their ordinary meaning. See *Western Union Tel. Co.* v. *Lenroot*, 323 U.S. 490, 503 (1945). An "article" would be defined merely as a 'thing" or "group of things" and would include "instruments, apparatus and contrivances". The definitions of the latter items are somewhat more specific, but all can be classified generally as "appliances".

An examination of plaintiff's suture products reveals that they are arguably either articles or instruments, ap-

paratus and contrivances. It is clear that the products fit into the broad definition of "articles". Less clear is whether such items could fit within the definition of "devices". Assuming *arguendo* that the products fit within both definitions, the remedial nature of the Food, Drug, and Cosmetic Act warrants a liberal construction for the protection of the public health and, thus, a finding that plaintiff's products are drugs. *Pasadena Research Labs., Inc.* v. *United States,* 169 F. 2d 375 (9th Cir.), cert. denied, 335 U.S. 853 (1948); *United States* v. *Kordel,* 164 F. 2d 913 (7th Cir. 1947), aff'd, 335 U.S. 345 (1948); see *United States* v. *Dotterweich,* 320 U.S. 277 (1943). The public will be better protected by classifying plaintiff's products as drugs rather than as devices so that proper testing, controlled by the Government, can be pursued. It would seem that where an item is capable of coming within two definitions, that definition according the public the greatest protection should be accepted.

Moreover, a "suture" is listed in XVII United States Pharmacopeia 691 (17th rev. ed. 1965). I do not agree with defendants that a listing in an official compendium is the crucial distinction between a drug and device. If this were correct, the clause in § 201(g) of the Act, 21 U.S.C. § 321(g) that the drug definition "does not include devices" becomes meaningless. The mere fact that an item is listed in the United States Pharmacopeia does not necessarily mean that such item is a drug for purposes of the Act. Cf. *FTC* v. *Liggett & Myers Tobacco Co.,* 108 F. Supp. 573 (S.D.N.Y. 1952), aff'd per curiam, 203 F. 2d 955 (2d Cir. 1953). On the other hand, the listing of an item in an official compendium should be some evidence that such item is a drug. The Krantz affidavit submitted by plaintiff is not relevant. Whether the compilers of the United States Pharmacopeia consider a particular item a drug or device given its ordinary meaning does not determine whether such item is a drug or device under the Act.

Accordingly, the Court is of the opinion that in considering the above factor, the necessary conclusion is that plaintiff's products are drugs.[2]

Classification of the Suture as a New Drug

§ 201(p) of the Act, 21 U.S.C. § 321(p), provides in pertinent part that a "new drug" is

> (1) Any drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof . . .

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[2] I have taken into consideration H.R. 10725[6], 90th Cong., 1st Sess. (1967), a Bill introduced June 8, 1967, which would require pre-market clearance where the device is one

> intended to be secured or otherwise placed, in whole or in part, within the human body or into a body cavity, or directly in contact with mucous membrane, and is intended to be left in the body or such cavity, or in such direct contact, permanently, indefinitely, or for a substantial period or periods.

Plaintiff claims that this Bill would clearly apply to its products and this can only be interpreted to mean that at present, pre-market clearance is not required for the sutures. It would appear that this proposed statute would be inapplicable in the instant case and would apply to those items which are clearly medical devices rather than to products which are arguably drugs and devices. An example of the former would be a surgical nail used for stabilizing broken bone fragments. See *Orthopedic Equip. Co.* v. *Eutsler*, 276 F. 2d 455 (4th Cir. 1960). I might note that in *Eutsler* it was unimportant whether the product was considered a drug or a device since the action was one for mislabeling and the liability which attached was equally applicable to either category. See §§ 301, 501, 502 of the Act, 21 U.S.C. §§ 331, 351, 352. In addition, the product was not listed in an official compendium.

21 C.F.R. § 130.1(h) provides in relevant part that

> The newness of a drug may arise by reason (among other reasons) of:
>
> . . .
>
> (5) The newness of a . . . method . . . of administration . . . prescribed, recommended, or suggested in the labeling of such drug, even though such drug when used in . . . other method . . . of administration . . . is not a new drug.

It is admitted that plaintiff's products constitute a new and unique method of administration of the suture. Defendants claim that such administration of the suture is not recognized among qualified experts as safe and effective for use in ligating vessels during surgery in that there may be a carcinogenic reaction to the suture and the button, that the possibility of breakage or slippage after application exists, that such breakage or slippage would result in internal bleeding, and that problems exist with respect to the maintenance of the sterility of plaintiff's products. Plaintiff alleges that the products have been tested and found safe but there is no allegation that the position taken by the experts within the Food and Drug Administration is unreasonable.

> "Where there is a genuine difference of medical opinion among the experts on the question of whether a drug is generally recognized as safe for the treatment of a particular disease, it must be concluded that the drug is not *generally* recognized as safe for use in the treatment of that disease." *Merritt Corp.* v. *Folsom*, 165 F. Supp. 418, 421 (D.D.C. 1958).

The difference of opinion does not create a material issue of fact which would require the denial of the summary judgment motions. For such difference indicates precisely the lack of general recognition of the safety of plaintiff's

products which brings them within the statutory definition of new drugs. *United States* v. *354 Bulk Cartons . . . Trim Reducing-Aid Cigarettes*, 178 F. Supp. 847, 852-53 (D.N.J. 1959); *Merritt Corp.* v. *Folsom, supra.*

Conclusions

The Court has determined that the products in issue are sutures and that such sutures are drugs. Since the method of administration of plaintiff's drugs is new and there is lack of general recognition of the safety of the sutures, they must be classified as new drugs.

Accordingly, plaintiff's motion for summary judgment is denied, defendants' cross-motion for summary judgment is granted, and the complaint is dismissed.

It is so ordered.

Dated: New York, New York
September 29, 1967

CHARLES H. TENNEY
U.S.D.J.

Judgment

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

67 Civ. 2115

AMP INCORPORATED, *Plaintiff*,

v.

JOHN W. GARDNER, Secretary of Health, Education and Welfare; and JAMES L. GODDARD, Commissioner of Food and Drugs, *Defendants*.

The plaintiff having moved for summary judgment, and the defendants having cross-moved for summary judgment, and the said motions have come on to be heard before the Honorable Charles H. Tenney, United States District Judge, and the Court thereafter on September 29, 1967 having handed down its opinion denying the plaintiff's motion for summary judgment and granting the defendants cross-motion for summary judgment it is,

ORDERED, ADJUDGED and DECREED: That the defendants John W. Gardner, Secretary of Health, Education and Welfare; and James L. Goddard, Commissioner of Food and Drugs have judgment against the plaintiff AMP Incorporated dismissing the complaint herein.

Dated New York, N. Y.
October 2, 1967

JOHN J. OLEAN, JR.
Clerk

Opinion of the United States Court of Appeals for the Second Circuit

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

No. 258—September Term, 1967.
(Argued January 10, 1968 Decided February 13, 1968.)

Docket No. 31829

AMP INCORPORATED, *Plaintiff-Appellant*,

v.

JOHN W. GARDNER, Secretary of Health, Education and Welfare; and JAMES L. GODDARD, Commissioner of Food and Drugs, *Defendants-Appellees*.

Before: SMITH, KAUFMAN and HAYS, *Circuit Judges*.

Appeal from a summary judgment entered in the United States District Court for the Southern District of New York, Charles H. Tenney, *Judge*, declaring plaintiff's products to be "new drugs" within the meaning of section 201(p) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321(p).

Affirmed.

JAY L. SEITCHIK, Harrisburg, Pa. (Marshall M. Holcombe, Harrisburg, Pa.; William C. Conner of Curtis, Morris & Safford, New York, N. Y., on the brief), *for plaintiff-appellant*.

JAMES G. GREILSHEIMER, Asst. United States Attorney, So. District of New York (Robert M. Morgenthau, United States Attorney, and Martin Paul Solomon, Asst. United States Attorney; Paul Hyman, Attorney, Food and Drug Administration, on the brief), *for defendants-appellees*.

SMITH, *Circuit Judge*:

This appeal from a summary judgment presents the question whether two products manufactured by appellant,

AMP Incorporated, are "new drugs" within the meaning of the Federal Food, Drug and Cosmetic Act ("the Act"), 52 Stat. 1040 (1938), as amended, 21 U.S.C. §§ 301-392.

Both of the products are intended to be used in a new method of tying off, or ligating, severed blood vessels during surgery. The conventional ligating method is to hand-tie ligatures around severed vessels by means of a surgeon's knot (which is a reef knot). AMP's products both consist of a disposable applicator, a nylon ligature loop, and a nylon locking disk. In one product, the applicator is a hemostat; in the other, it is a long slender tube. The ligature is applied by inserting the hemostat or tube into the body and placing the loop around the severed vessel, then tightening the loop and locking it in place with the disk. The excess nylon thread is cut off, and the disk and the rest of the thread remain in the patient's body.

In response to a request by AMP for classification of its products, the Food and Drug Administration advised AMP that the products were regarded as "new drugs." Under section 505 of the Act, as amended, 21 U.S.C. § 355 (Supp. 1967), new drugs may not be introduced into interstate commerce without approval by the Secretary of Health, Education and Welfare. AMP subsequently decided to take the position that the products were "devices" rather than "new drugs" within the meaning of section 201(g), (h), and (p) of the Act, as amended, 21 U.S.C. § 321(g), (h), and (p) (Supp. 1967), and proceeded to comply with the requirements of the Act relating to devices.[1] Under threat of regulatory proceedings should it

[1] We reject, as did the District Court, AMP's argument that a letter of the Food and Drug Administration suggesting changes in labeling of the products submitted under the provisions of the Act relating to devices constitutes "tacit approval" of AMP's characterization of the products as "devices." See *AMP Incorporated* v. *Gardner*, 275 F. Supp. 410, 412 n. 1 (1967).

fail to comply with the statutory and regulatory requirements pertaining to drugs, AMP sought a judgment declaring its products to be devices and an injunction barring enforcement of the "drug" and "new drug" provisions of the Act against AMP or its ligating products.[2] The District Court for the Southern District of New York, Judge Tenney, determined that the products should be classified as "new drugs," and gave summary judgment for the defendants, John W. Gardner, Secretary of Health, Education and Welfare, and James L. Goddard, Commissioner of Food and Drugs. *AMP Incorporated* v. *Gardner*, 275 F. Supp. 410 (1967). We affirm, having concluded that the construction of the Act arrived at by Judge Tenney is essentially correct.

Section 201, as amended, provides in relevant part that for the purposes of the Act:

> (g)(1) The term "drug" means (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, of any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C) of this paragraph; but does not include devices or their components, parts, or accessories.
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> • • • • •

[2] The defendants concede that the declaratory judgment procedure is proper since there is a final determination by the Commissioner of Food and Drugs. See *Abbott Laboratories* v. *Gardner*, 387 U.S. 136, 87 S. Ct. 1507 (1967).

(h) The term "device" . . . means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals.

* * * * *

(p) The term "new drug" means—

(1) Any drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, ... or

(2) Any drug the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

We begin by conceding *arguendo* the validity of AMP's contention that the hemostat and the tube, taken alone, are "instruments" and thus "devices" within the meaning of the Act. But we do not agree that the nylon thread and disk are such "components, parts, or accessories" of the hemostat and the tube as to make them "devices" as well. As Judge Tenney pointed out by way of analogy, a syringe may be a "device" under the Act, but that does not make a drug in a syringe a "device" for purposes of the Act simply because it is packed for use in the syringe. It is

the thread and disk applied to the patient's body which are essential, and on which we must focus our attention.[3]

This would be an easy case were it not for the provision in section 201(g) that the term "drug" "does not include devices," for apart from that exclusion the Act's definition of "drug" is so broad as to cover easily AMP's nylon disk and thread.[4] The Act's definitions of "device" and "drug" are parallel, except for the use of "instruments, apparatus, and contrivances," rather than the broader word "articles," in defining "device."[5] In determining what things Congress meant to set apart as "instruments, apparatus, and contrivances," we take as our guide Judge Learned Hand's observation that "unless they explicitly forbid it, the purpose of a statutory provision is the best test of the meaning of the words chosen." *Cawley* v. *United States*, 272 F. 2d 443, 445 (2 Cir. 1959).

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[3] We would characterize the applicator as a "component" of the thread and disk, see section 201(g)(1)(D) of the Act, as amended, rather than vice versa.

The applicator is the embodiment of a new method of applying the ligature, which is the basis of the defendants' "new drug" conclusion. 21 C.F.R. § 130.1(h) provides: "The newness of a drug may arise by reason (among other reasons) of: . . . (5) The newness of a dosage, or method or duration of administration or application . . ." And see *Merritt Corporation* v. *Folsom*, 165 F. Supp. 418, 421 (D. Ct. D.C. 1958).

[4] The basic word of the definition is "article," which is defined as "one of a class of material things." Webster's Third New International Dictionary (1963).

[5] The only other significant difference between the definitions is that the "device" definition does not include listing in the Pharmacopoeias or the National Formulary. See note 12, *infra*, and accompanying text.

We note the dictionary definitions of the words used: for "instrument," "utensil" or "implement"; for "contrivance," "a mechanical device"; and for "apparatus," "any compound instrument or appliance designed for a specific mechanical or chemical action or operation." Webster's Third New International Dictionary (1963).

In the early versions of the Act, there was no separate definition of "device." S. 2800, 73d Congress, 2d Sess. (1934), as reported by the Senate Committee on Commerce, provided in section 2(b):

> The term "drug," for the purposes of this Act and not to regulate the legalized practice of the healing art, includes (1) all substances and preparations recognized in the United States Pharmacopoeia, Homoeopathic Pharmacopoeia of the United States, or National Formulary or supplements thereto; and (2) all substances, preparations, and *devices* intended for use in the cure, mitigation, treatment, or prevention of disease in man or other animals; and (3) all substances and preparations, other than food, and all *devices* intended to affect the structure or any function of the body. [Emphasis added.]

See also S. 1944, 73d Congress, 1st Sess. (1933), and S. 2000, 73d Congress, 2d Sess. (1934).

Senator Copeland, who introduced all three bills, said in his prepared statement introducing S. 2800:

> The present law defines drugs as substances or mixtures of substances intended to be used for the cure, mitigation, or prevention of disease. This narrow definition permits escape from legal control of all therapeutic or curative devices like electric belts, for example. It also permits the escape of preparations which are intended to alter the structure or some function of the body, as for example, preparations intended to reduce excessive weight. There are many worthless and some dangerous devices and preparations falling within these classifications. S. 2800 contains ample authority to control them.

78 Cong. Rec. 8960 (73d Cong., 2d Sess., 1934). S. 2800 contained no provisions relating to new drugs, and did not

require administrative approval of any products prior to their introduction into interstate commerce.

S. 2800 was succeeded by S. 5, 74th Congress, 1st and 2d Sess. (1935-36). That bill, as introduced in the Senate, included a definition of "drug" almost identical to that in the earlier bill. The definition drew some criticism during Senate debate over an amendment (which eventually passed) to insert the word "diagnosis" so as to make the definition read in part:

> All substances, preparations, and devices intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals.

79 Cong. Rec. 4841-4845 (74th Cong., 1st Sess., 1935). Senator Clark (Missouri) questioned the propriety of calling purely mechanical devices "drugs":

> [I]f the devices ought to be outlawed, they ought to be outlawed, and I have no objection to that; but to maintain that a purely mechanical device is a drug and to be treated as a drug in law and in logic and in lexicography is a palpable absurdity, in my opinion.

Id. at 4841. The following exchange subsequently took place between Senators Clark and Copeland:

> MR. CLARK . . . The effect of the amendment [inserting the word "diagnosis"] is to declare by Federal law the scales used by a physician to test the weight of patients in connection with a diagnosis to be a drug . . .
>
> MR. COPELAND. Mr. President, I desire to state the effect of this amendment.
>
> There are on the market certain electrical devices. A man takes hold of the handles of the machine, and the indicator spins around. It stops at "appendicitis,"

> or it stops at "meningitis" . . . Such a device is manifestly a fraud upon society.
>
> That is what the amendment is designed to deal with.

Id. at 4842.

The result of the criticism of calling certain mechanical devices "drugs" voiced on the Senate floor was that when the bill returned to the Senate Committee on Commerce, it was amended to add a parallel definition of devices.[6] This amendment was agreed to by the Senate without debate. 79 Cong. Rec. 8351-8355 (74th Cong., 1st Sess., 1935). The change was explained by Walter G. Campbell, Chief of the Food and Drug Administration, during hearings held on S. 5 by a subcommittee of the House Committee on Interstate and Foreign Commerce:

> The purpose of the third subdivision is to provide for "devices." Originally, this definition of "drugs" also included devices, such as mechanical appliances and contraptions which are to be found without number. But the incongruity of classifying certain devices, such as the electric belt, therapeutic lamps, and so forth, as drugs was pointed out by the Senate in the last consideration of the bill. They felt it proper to provide an independent definition of "devices." . . .

Hearings on S. 5 Before a Subcommittee of the House Committee on Interstate and Foreign Commerce (74th Cong., 1st Sess., 1935).[7]

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[6] The substitute committee report contained no explanation of the amendment, merely noting: "A definition of devices is provided paralleling that of drugs. This expansion of the definition of the term 'drug' and the inclusion of devices are essential if the consumer is to be protected against a multiplicity of abuses not subject to the present law." Sen. Rpt. No. 646, 74th Cong., 1st Sess. (1935). This report is reprinted in Dunn, Federal Food, Drug, and Cosmetic Act—A Statement of Its Legislative Record, 477 (1938), which contains most of the Act's legislative history.

[7] In Dunn, *op. cit. supra*, at 1235, 1247.

We have found nothing in the legislative history of the Act indicating that the Congressional purpose in providing a separate definition of "devices" was anything other than to avoid the incongruity of classifying such things as electric belts as "drugs." There was at the time no practical significance to the distinction between "drugs" and "devices," for the operative provisions of the bill (*e.g.*, the provision barring the introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded) applied identically to both.[8] The bill, as late as August, 1937, included no section relating to "new drugs," and no requirement that any products covered by the bill be submitted to the government for prior approval before their introduction into interstate commerce.[9]

The bill might well have been enacted without any prior approval sections had it not been for the "Elixir Sulfanilamide" tragedy of September-October, 1937.[10] As a direct consequence of that experience, involving the deaths of nearly one hundred persons across the nation who had consumed an untested drug preparation, bills supplementing S. 5 were introduced in the 75th Congress, 2d and 3d Sess. These new bills included prior approval provisions sub-

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[8] For a time, section 401 referred only to "adulterated drugs," but that was presumably an oversight, since the operative provision, section 706(a)(1), barred the introduction into interstate commerce "of any food, drug, device, or cosmetic that is adulterated or misbranded." See Dunn, *op. cit. supra*, at 532, 537, 544.

S. 5 died in the House, *Id.* at 633, but was succeeded by S. 5, 75th Cong., 1st and 3d Sess. (1937-38). By August, 1937, the bill had been changed to refer throughout both to "adulterated drugs" and "adulterated devices." *Id.* at 752-773.

[9] *Ibid.*

[10] See Report of the Secretary of Agriculture on Deaths Due to Elixir Sulfanilamide-Massengill [Submitted in response to S. Res. 194 of November 16, 1937], in Dunn, *op. cit. supra*, at 1316-1327.

stantially similar to the "new drug" provisions of the Act.[11] When those provisions were incorporated in S. 5 and enacted as part of it, sections 201(p) and 505, the term "new drug" was used, so far as we can determine, without any attention to the fact that the distinction between "drug" and "device" had thus for the first time become important.

Since the only significance in classifying AMP's products as either "drugs" or 'devices" is that if they are "drugs" they may be subject to the "new drug" provisions of the Act, we must classify them with reference to the purpose for which Congress enacted those provisions. That purpose was, very clearly, to keep inadequately tested medical and related products which might cause widespread danger to human life out of interstate commerce. The product which immediately precipitated Congressional concern —"Elixir Sulfanilamide"—was a drug within the everyday, narrow sense of the word, but we would hardly suppose that when Congress incorporated the "new drug" bills resulting from the "Elixir Sulfanilamide" tragedy into an Act which contained an extremely broad definition of the word "drug," it intended that the operation of those provisions should be restricted to products commonly called "drugs," and that products such as ligatures, which might present the very dangers the provisions were designed to meet, should be excluded. We would, moreover, be reluctant to give a narrow construction to this statute, touching the public health as it does. Cf. *United States* v. *Dotterweich*, 320 U. S. 277, 281 (1943). AMP's ligatures are of nylon suture material of the type recognized in the United States Pharmacopoeia, 691 (17th rev. ed. 1965), and such suture material has always been regarded as "drugs" by the Food

[11] S. 3073, 75th Cong., 2d and 3d Sess., and H. R. 9341, 75th Cong., 3d Sess. For development of the Senate Bill see 82 Cong. Rec. 585 (75th Cong., 2d Sess., 1937), and 83 Cong. Rec. 1682, 6263-64, and 6423 (75th Cong., 3d Sess., 1938).

and Drug Administration.[12] The exclusionary classification "devices" should, we think, be limited to such things as Congress expressly intended it to cover. The language of section 201(g) plainly permits calling AMP's nylon thread and disk, in their intended use, "drugs," and we hold that that is their appropriate classification.

It remains to consider whether AMP's products are "new drugs" within the meaning of section 201(p) of the Act, and whether this was an appropriate case for summary judgment.

Defendants submitted the affidavit of William J. Gyarfas, M.D., Acting Director of the Division of Dental and Surgical Adjuncts, Office of New Drugs, Bureau of Medicine, in the Food and Drug Administration. He stated:

> It is my considered judgment that AMP's ligating products constitute a unique method of administration of the ligature which is not now and never has been generally recognized as safe and effective, among experts qualified by scientific training and experience to evaluate the safety and efficacy of such drugs, for use in ligating bleeding vessels during surgery.

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[12] We cannot accept the distinction argued for by AMP between a suture, which sews human tissue, and a ligature, which ties it. As the District Court noted, the exclusion clause of section 201(g) of the Act prevents listing in the Pharmacopoeia from being conclusive on the classification issue.

We note that the term "devices" was included in the Act in order to cover products not covered by the existing law (see, e.g., note 6 *supra*), that the term "drug" was defined by the existing law as a "substance . . . intended to be used for the cure, mitigation, or prevention of disease of either man or other animals" (Pure Food and Drugs Act of 1906, section 6, 34 Stat. 769), and that this court held gauze bandages to be a "drug" covered by that Act. *United States* v. *48 Dozen Packages, More or Less, of Gauze Bandage Labeled in Part Sterilized*, 94 F. 2d 641 (2 Cir. 1938).

> • • • Since sutures remain implanted in the body, long-term toxicity studies are required prior to approval. These long-term toxicity studies must be made with respect to the fate of the implant in order to demonstrate that there occurs neither irritation nor carcinogenic (cancer-producing) reaction to the implant . . . [I]t is known that the size and shape of an implant may affect its carcinogenic properties . . .

AMP submitted the affidavit of Curtis P. Artz, M.D., Professor of Surgery and Chairman of the Department, Medical College of South Carolina, who stated:

> That since January 1, 1966, I have conducted extensive pre-clinical and clinical studies of [AMP's] ligating instrument to determine the ease of placement, holding characteristics, and tissue reaction of the instrument.
>
> That . . . the results show the AMP ligating instrument to be an effective device which aids a surgeon during a surgical procedure. The instrument . . . produces no adverse tissue reaction.
>
> • • • • •
>
> The instrument produces no pharmacological action and is used only as a mechanical clamp.

On the basis of these two affidavits, we must conclude that AMP's products are "not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof . . . ," and are therefore "new drugs" within the meaning of Section 201(p) of the Act.[18]

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[18] Under settled administrative practice the entire product (the applicator as well as the disk and thread) must be submitted for the Secretary's approval. See note 3, *supra*.

This is, we think, an appropriate case for summary judgment. Cf. *United States* v. *354 Bulk Cartons * * * Trim Reducing-Aid Cigarettes*, 178 F. Supp. 847 (D. N. J. 1959). While we would not necessarily accept the defendants' position that whenever a court in a case such as this one is presented with a genuine difference of opinion among experts as to a drug's safety and effectiveness, that case is ripe for summary judgment, we agree that on the affidavits' presented here there remained no genuine issue of material fact to be tried.[14] AMP contends that the defendants' motion for summary judgment should not have been granted because there remained an issue as to the safety and efficacy of AMP's products. But the safety of the products is not what is at issue here. The question is whether there is general recognition among qualified experts of the products' safety and effectiveness—if there is not, the products must be submitted to the Secretary of Health, Education and Welfare for a determination as to safety, adequacy of testing, etc.[15] Since the affidavit submitted by AMP was addressed only to one doctor's opinion of the safety of the products, whereas the affidavit of Dr. Gyarfas was addressed to the issue of general recognition of the products' safety, and it does not appear that AMP was denied the opportunity to supplement the affidavit of Dr. Artz with depositions, answers to interrogatories, or further affidavits (see Rule 56(e), Fed. Rules Civ. Proc.), we must conclude that no issue of material fact remained to be tried.

Affirmed.

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[14] Defendants' position might create problems in some cases involving affidavits presenting not only a difference of opinion as to a drug's safety, but also a difference of opinion as to whether the drug is generally recognized as safe.

[15] The safety of AMP's products may yet be considered in Federal Court, for section 505 provides for judicial review of administrative action—see 21 U.S.C. § 305(h) (Supp. 1967).

Judgment

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

At a Stated Term of the United States Court of Appeals, in and for the Second Circuit, held at the United States Courthouse in the City of New York, on the thirteenth day of February one thousand nine hundred and sixty-eight. Present:

HON. J. JOSEPH SMITH, HON. IRVING R. KAUFMAN, HON. PAUL R. HAYS, *Circuit Judges.*

AMP INCORPORATED, *Plaintiff-Appellant,*

v.

JOHN W. GARDNER, Secretary of Health, Education and Welfare, and JAMES L. GODDARD, Commissioner of Food and Drugs, *Defendants-Appellees.*

Appeal from the United States District Court for the Southern District of New York.

This cause came on to be heard on the transcript of record from the United States District Court for the Southern District of New York, and was argued by counsel.

ON CONSIDERATION WHEREOF, it is now hereby ordered, adjudged, and decreed that the judgment of said District Court be and it hereby is affirmed.

A. DANIEL FUSARO
Clerk

APPENDIX C

Conflicting Opinion

No. 17592

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

UNITED STATES OF AMERICA, *Plaintiff-Libellant, Appellant,*

v.

AN ARTICLE OF DRUG * * *
BACTO-UNIDISK * * *,
Defendant-Claimant, Appellee

ON APPEAL from the United States District Court for the Eastern District of Michigan, Southern Division.

Decided March 29, 1968.

Before: COMBS, Circuit Judge, MCALLISTER and CECIL, Senior Circuit Judges.

CECIL, Senior Circuit Judge. This appeal involves a product known as Bacto-Unidisk which is described as a circular one-half inch wide cardboard having a diameter of just over three and one half inches, with eight circular paper units extending inwardly from the ring. Seven of these units are impregnated with different antibiotic drugs and the eighth one with sulfadiazine. The disc is referred to as a sensitivity unit.

The action arose out of condemnation of a quantity of the product by the United States under the Food, Drug and Cosmetic Act, Section 301 et seq., Title 21, U.S.C. The government claims that the product (1) is a "drug" within

the meaning of the Act, (2) is composed partly of specified antibiotic drugs, (3) was shipped in interstate commerce, and (4) was neither certified nor exempted from certification, as required by Section 357, Title 21, U.S.C. This failure to obtain certification or exemption from certification, was alleged to render the product misbranded under Section 352(1), Title 21, U.S.C.

The threshold question is whether Bacto-Unidisk, the product in question, is a drug within the meaning of Section 321(g), Title 21, U.S.C. That section provides

> "The term 'drug' means (1) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (3) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (4) articles intended for use as a component of any article specified in clauses (1), (2), or (3) of this paragraph; but does not include devices or their components, parts, or accessories."

The district judge held that it was not a drug as defined in the Act. We agree.

It is conceded that no part of the disc, which is the subject of the action, is administered to man or other animals, either internally or externally. It is used in hospital laboratories and in clinical practice to test the sensitivity or reaction of a specimen drawn from a patient to each of the antibacterial units contained on the disc—hence, the reference, sensitivity disc. The patient's specimen may be sputum, urine, throat swab or other matter withdrawn from his body. The sole function of the disc is to furnish medical doctors with information which enables them to treat diseases previously diagnosed.

If the statute has any application, it would have to be under subdivision (2), "articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals; * * *" The district judge said in his opinion, "When it comes right down to the determination which we must make, a literal reading of (g)(2) which defines 'drug' as 'articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals' clearly has application to the article libeled herein." This is only true in an indirect sense. Certainly it has nothing to do with diagnosis or prevention of disease. In itself it is not intended for use either internally or externally to cure, mitigate or treat disease. It only aids the physician to determine what antibiotics to use for the cure, mitigation or treatment of the patient's disease. We agree with the trial judge that it was not the legislative intent to apply the phrase "intended for use in the * * * cure, mitigation, treatment * * *" in such an indirect manner.

The district judge made Findings of Fact and Conclusions of Law. Finding of Fact 9 and Conclusion of Law 3 are as follows:

> "9. Sensitivity disks are not recognized in (admitted to) the United States Pharmacopeia or the National Formularly, which are 'official compendia' under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321 (j)) nor are such disks the kind of articles which are accepted for admission to the official compendia because, among other reasons, they are not regarded by the Committees on Revision (admission) of the compendia as drugs within the commonly accepted meaning of that term in medical science. In medical science those substances which are for administration to or for use on, a person for the treatment of disease or injury, are regarded as drugs. This is the commonly accepted view of physicians generally. A physician who testified for libellant could think of no example of a sub-

stance not taken into or applied to the body which he would 'consider medically' as a drug."

"3. In medical science the concept of 'drug' is limited to articles administered to man or other animals, either internally or externally. This is the generally accepted view among physicians (Finding Number 9). The evidence affords no basis for the conclusion that the definition of 'drug' in the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321(g)) was intended by Congress to extend beyond the meaning of that term in medical science, to encompass these sensitivity disks. The definition of 'drug' is found in 21 U.S.C. 321(g).

We agree with the district judge and conclude that the Bacto-Unidisk, which is the subject of this action, is not a drug within the meaning of Section 321(g), Title 21, U.S.C. and is therefore not from a batch of antibiotic drugs to which a certificate or release is required pursuant to Section 357(a), (c), Title 21, U.S.C.

Authorities cited by counsel for appellant to the effect that such substances as honey, mineral water, cigarettes, peppermint leaves and human blood have been held to be drugs are not in point. Section 321(g), Title 21, U.S.C. defines "drug", in part, "as an article '*intended for use*' in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals." (Emphasis added.) In holding honey,[1] mineral water,[2] cigarettes[3] and peppermint tea leaves[4] to be drugs, the courts based their opinions on the fact that by advertising these products as

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[1] *United States* v. *250 Jars . . . Honey,* 218 F. Supp. 208 (E.D. Mich., aff'd 344 F. 2d 288 (C.A. 6).

[2] *Bradley* v. *United States,* 264 Fed. 79 (C.A. 5).

[3] *United States* v. *46 Cartons . . . Fairfax Cigarettes,* 113 F. Supp. 336 (D.N.J.).

[4] *United States* v. *Hohensee,* 243 F. 2d 367 (C.A. 3), cert. den. 353 U.S. 976, rehearing den. 354 U.S. 927.

possessing therapeutic and medicinal powers, such products were "intended for use" as drugs and hence within the statutory definition. Whole human blood[5] which may be used in human blood transfusions clearly comes within the meaning of the statute.

Another question raised at the trial level and assigned as error on this appeal is that the claimant should be barred from raising the question that the seized article is not covered by the statute for the reason that it had not availed itself of permissible administrative procedure.

The Food and Drug Administration has attempted in Part 147 of its regulations (21 C.F.R. 147 et seq.) to issue regulations applicable to sensitivity discs such as Bacto-Unidisks. The appellant claims that inasmuch as the claimant, after due notice, failed to seek judicial review of the above regulations, as provided by statute, he cannot collaterally attack their validity in an enforcement proceeding. See *Byrd* v. *United States,* 154 F.2d 62 (C.A. 5); *United States* v. *Bodine Produce Co.,* 206 F. Supp. 201 (D. Ariz.). However, unlike those cases which involved regulations pertaining to articles which were concededly within the jurisdiction of the Food and Drug Administration, the issue in this case is whether Bacto-Unidisk is a drug within the meaning of the statute and therefore not subject to any regulation of the Food and Drug Administration. Our function on this appeal is not to review the validity of the regulations to determine if they are supportable by substantial record evidence and not an abuse of administrative discretion, but to determine, based upon an interpretation of the statutory definition of a drug, whether the seized article is within the Administrator's jurisdiction. A claimant cannot be precluded from defending a libel action on the ground that the seized article is not covered by the statute.

The judgment of the District Court is affirmed.

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[5] *United States* v. *Calise,* 217 F. Supp. 705 (S.D.N.Y.).

APPENDIX D

FDA Fact Sheet

U. S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

FACT SHEET: *Medical Device Safety Act of 1967*

NEED

Revolutionary advances in the development of medical devices have taken place since the original enactment of regulatory legislation in this field nearly 30 years ago.

These achievements in medical technology have introduced a broad array of devices that are new, not only in purpose and usefulness, but often in the very materials used in their manufacture.

Surgical implants, contact lenses, artificial kidneys, and nylon arteries are examples of the significant advances that have taken place in recent years. The current progress in the development of artificial hearts is still another momentous forward step.

This research and innovation must be encouraged to insure the further development of life-saving devices. At the same time, the patient as well as the physician is entitled to the assurance that a particular device has been adequately tested and proved safe, reliable, and effective. In the case of devices, such assurance cannot be given under existing law. At the present time, physicians and medical devices purchasing personnel must rely almost entirely on a manufacturer's representations as to the vital information about a new medical device. This involves a description of the materials in the device, expected parts obsolescence, breakdown and servicing rates, and other technical data. No Federal law requires advanced proof of safety, reliability, and effectiveness before a device reaches the market. Action can be taken only after injury has occurred or the Government can develop other proof that the device is not safe, reliable, and effective. Appro-

priate legislation, with sufficient safeguards to protect research, innovation and development, should be introduced now to close this gap.

PROPOSAL

The Medical Device Safety Act of 1967, in effect, divides medical devices into three classes; first, those devices which would be safe when manufactured under standards (e.g.: bone pins, catheters, X-ray equipment, and diathermy machines); second, those devices, such as artificial kidneys and other organ substitutes, that would go through a clearance procedure before being put on the market; third, common patient-care devices not requiring any regulation.

Standard-Setting Authority

To protect the public health and safety, the Secretary of Health, Education, and Welfare would be authorized to establish mandatory standards relating to the composition, properties, or performance of a medical device or class of medical devices. Diagnostic devices would be specifically excluded from the standard-setting authority.

In the development of the standard, "the Secretary shall to the optimum extent consult" with appropriate Federal agencies concerned with standard-setting, with other standard-setting organizations, and with nongovernmental experts. The proposal calls for conferences, work-shops, and other means by which nongovernmental experts could fully participate in the development of the standard.

Any person who would be adversely affected by a standard could require the referral of the matter to an independent advisory committee of experts nominated by the National Academy of Sciences, for a report and recommendations.

The right to a hearing and to court review would be available to anyone affected by a standard.

It is expected that such standards would be modified periodically to keep pace with advances in scientific and clinical knowledge.

Premarket Clearance

The proposal calls for the premarket clearance of a device (other than diagnostic and veterinary devices) if (1) the device is not generally recognized by qualified experts as safe, reliable and effective *AND* "(2) such device (A) is intended to be secured or otherwise placed, in whole or in part, within the human body or into a body cavity, or directly in contact with mucous membrane, and is intended to be left in the body or such cavity, or in such direct contact, permanently, indefinitely, or for a substantial period or periods (as determined in accordance with regulations issued after notice and opportunity to present views), or (B) is intended to be used for subjecting the human body to ionizing radiation, electromagnetic, electric, or magnetic energy (including, but not limited to, diathermy, laser, defibrillator, and electroshock instrumentation), or heat, cold, or physical or ultrasonic energy, or is intended for physical or radio- or electronic or electric communication in either direction with any part of the human body or with a device placed within or connected with the human body, or (C) is a device which the Secretary, by special order made on the basis of a finding (for reasons stated in the order) that there is probable cause to believe that the device is not effective for its use or intended use or that it is not safe for use under the conditions prescribed, recommended, or suggested in its labeling, has declared to be subject to the requirements of this subsection with respect to such use or intended use, . . ." (See "exemptions" below)

Any person who would be adversely affected by the premarket clearance procedure could require the referral of the matter to an independent advisory committee of ex-

perts nominated by the National Academy of Sciences, for a report and recommendations.

The right to a hearing and to court review would be available to the applicant for premarket clearance.

The proposal would require the establishment, to the extent practicable, of a list of devices that are found to be generally recognized by experts as safe, reliable, and effective for use, and hence not subject to premarket clearance.

Exemptions

(1) There would be a broad exemption from regulation for devices under clinical investigation. No notice of the investigation would have to be given until the development of the device has reached a point at which separate groups of investigators working with a sponsor are following essentially the same plan in developing data required to support an application for premarket clearance. At that point, a plan of investigation would have to be submitted by the sponsor to FDA. In determining the need for and the adequacy of the plan, there would be opportunity for consultation with appropriate non-FDA experts.

(2) Devices complying with standards established under the proposal would be exempt from preclearance, if the standard covers all relevant aspects.

(3) The Secretary would also be authorized to exempt from preclearance those devices for which it is feasible to establish an adequate standard within a reasonable time.

(4) Custom-made prescription devices would not be subject to preclearance.

(5) Custom-made devices made to the specifications of a licensed practitioner for his use would be excluded from preclearance.

Other Provisions

The proposal would require the maintenance of current good manufacturing practice by device manufacturers. It would also provide for registration of device manufacturers, inspection, and appropriate record keeping as to experience had with a device which is subject to a standard or which has been approved for the market.

The preclearance requirement of the law would become generally effective a year after the month of enactment. However, in the case of devices already on the market when the bill becomes law, the preclearance requirement would become generally effective 2½ years after the month of enactment, and the Department could further postpone the effective date in the case of a particular device for up to an additional 2½ years if necessary for completion of the required scientific research.

The law would be administered by the Food and Drug Administration with advice, on general policy matters, of an Advisory Council on Devices and in consultation with other governmental agencies.

APPENDIX E

Letter from the FDA to Rep. Jarman

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
FOOD AND DRUG ADMINISTRATION
WASHINGTON, D. C. 20204

September 25, 1967

Honorable John Jarman
House of Representatives
Washington, D. C. 20515

Dear Mr. Jarman:

This is in reply to your letter of August 25, 1967, concerning H.R. 10726, "The Medical Device Safety Act of 1967."

While it is true that the definition of "device" in the Federal Food, Drug, and Cosmetic Act is an extremely broad one, the range of devices subject to preclearance and standard setting in H.R. 10726 is considerably narrower. Knowing that the scope of the required preclearance was a major stumbling block to this much needed legislation, we made a very special effort to carefully delineate and narrow the new definition, with the objective of requiring preclearance only where it was plainly needed.

To this end, we proposed exemption of all diagnostic devices. We proposed exemption of all therapeutic and prophylactic devices that are generally recognized among qualified experts as safe and effective for their intended uses. And we proposed that standards be promulgated for a number of other devices which would assure performance characteristics under which they could be generally recognized as safe and effective, and thus be exempted from preclearance. And finally we proposed exemption of custom made and prescription devices specially prepared to order and of investigational devices being studied by qualified investigators in the earliest stages of develop-

ment. All of this was to meet the contention that the bill would require preclearance of some devices for which there was no need in the public interest.

We were quite specific as to the type of devices that would require preclearance. These are devices implanted in the body cavities, placed in contact with mucous membranes for protracted periods, devices delivering forms of energy to the body, such as laser devices, and devices implanted in the body for communication with electronic or similar equipment. As to devices not within these specifications, we retained the right to make a finding that there was probable cause to believe they were not safe or not effective for their intended purposes, and by such finding to require the submission of data on the devices for preclearance. This is to cope with unsafe and ineffective devices now or hereafter being marketed.

All of this, we believe, makes this a realistic proposal which goes no further than the protection of the patient requires.

In response to requests from the industry during our preliminary discussions of the proposal, a provision was inserted to require the Secretary to establish a list of devices which he regarded as generally recognized as safe and effective. This requirement will effectively provide the industry with a positive guideline in determining those devices subject to preclearance. Establishment of such a list will be an extremely difficult task, and we have solicited the industry to assist in the preparation of a tentative list (a copy of a letter sent to representatives of the industry is enclosed).

We have, however, for descriptive purposes compiled a brief list of devices which we believe would be subject to the various sections of the bill. A copy of these lists are enclosed. When more expansive lists are developed, we will be sure to forward a copy to you.

We cannot now specify all of the devices which cause us special concern. We believe that all devices which are placed in or on the body or which impart energy to the body should be properly tested prior to marketing. In the absence of a statutory requirement for pre-market testing, we believe the exigencies of the competitive market alone foments testing below the level to which the patient is entitled.

We have isolated several examples of faulty devices such as nylon hip prosthesis, bone pins, artificial eyes, and artificial kidney machines. However, our ability to detect such inadequacies is significantly hampered by our lack of authority (inspection, records and reports, etc.) and the hesitancy of physicians to report because of the possibility of negligence actions. Consequently, we believe the preclearance requirement has been limited to those devices which of their nature command prior testing.

Replying to your specific questions:

1. What other Federal agencies, or other nationally or internationally recognized agencies, does the Secretary plan to consult in setting standards under Title I, and on what standards would such consultation occur?

Federal agencies which have established standards for devices include the Department of Defense, National Bureau of Standards, and the Veterans Administration. A list of voluntary organizations involved in standards setting for devices is enclosed.

We contemplate utilizing outside expertise in the development of virtually every standard. As the bill states, "the Secretary shall to the optimum extent consult with, and give appropriate weight to relevant standards published by, other Federal agencies concerned with standard setting or other nationally or internationally recognized standard-setting agencies or organizations, and invite appropriate participation,

through joint or other conferences, workshops, or other means, by informed persons representative of scientific, professional, industry, and consumer organizations that in his judgment can make a significant contribution to such development."

2. What devices would fall within the provision of the proposed new Section 513 so as to require pre-marketing clearance?

See lists enclosed.

3. If the Secretary finds under Section 513(a)(2)(C) that there is probable cause to believe that any device is not safe or effective, so as to require pre-marketing clearance, is there not ample authority under present law to proceed against such device and its manufacturer?

Presently, to sustain regulatory action against a particular device, we must establish in Court that a device is "adulterated" or "misbranded." The "probable cause" basis would, we believe, be a substantially lesser burden to establish. And its offset would not put the devices off the market; it would call for the submission of scientific data to resolve the doubts.

4. What type of devices would you expect the Secretary to exempt under the proposed Subsections 513 (K) and 513(l)?

5. Does paragraph 1 of Subsection 513(K) contemplate that a particular device might be subject to both an established standard and a requirement for pre-marketing clearance?

Any device for which a standard has been established would be exempt from preclearance. The parenthetical language is designed to cover a device which has a standardized device as a constituent part. This language would, for example, permit preclearance of a

device utilizing a material which has been standardized (perhaps for use in various devices) thereby alleviating duplicative preclearance of such material for use in each device. The preliminary lists enclosed indicate those devices for which standards are contemplated. Presumably, this section could be interpreted to subject a device to both preclearance and standards. However, it is intended that a device subject to a standard would be exempt from preclearance. We believe this mandate is implicit in the language except in, at most, isolated circumstances.

6. Does paragraph 1 of Subsection 513(l) contemplate pre-marketing clearance of devices licensed by the Atomic Energy Commission?

The AEC enforces numerous controls over the manufacture and use of machines utilizing atomic energy. Cobalt irradiators, for example, could thus be subject to dual regulation. This provision (513(l)) would exempt such machines from preclearance to the extent they are regulated by AEC. The regulation by AEC is primarily directed to the protection of the users, thus we could, in most cases, avoid this consideration under our preclearance of such devices. The provision is also necessary to prevent any future conflict between our respective areas of responsibility.

In our opinion, this legislation provides essential safeguards to protect the public interest without calling for unreasonable burdens on the affected industry. The broad exemption for investigational devices (as opposed to that for drugs) reflects our concern for the position taken by many scientists in the field. The requirement for a list of exempt devices was included at the request of the industry so as to enable them to readily determine the extent of the exemption for devices generally recognized as safe and effective.

The total exemption for diagnostic devices also demonstrates our desire not to impose any undue burden.

For your further information, I am enclosing a copy of a speech I presented before the Medical Surgical Marketing Group.

If we can be of any further assistance, please let us know.

Sincerely yours,

PAUL A. PUMPIAN, Director
Office of Legislative and
Governmental Services

Enclosures

EXAMPLES OF TYPES OF DEVICES WHICH THE FOOD AND DRUG ADMINISTRATION BELIEVES MAY BE SUBJECT TO PRECLEARANCE PRIOR TO COMMERCIAL DISTRIBUTION

These include devices (1) which embody new principles of physics or biology, (2) which were previously exempted or had established standards but now have new therapeutic uses which would require preclearance until standards could be written or until experts qualified by training and experience are satisfied that they were exempt, (3) which are constructed of new materials for which there are no standards.

Examples of these are:

Laser Devices.

This embodies a light principle which may be incorporated into literally hundreds of devices with use in everything from cancer chemotherapy to blood coagulation.

Cardiac Pacemakers.

Heart Valves.

Synthetic Blood Vessels.

Contact Lenses.

Implants and Prosthesis of metal and plastic.

Artificial Heart.

Aritficial Kidney.

Suture Material with previously unknown medical applications.

Energy Devices with new applications such as ultrasound.

EXAMPLES OF TYPES OF DEVICES WHICH SHOULD BE THE SUBJECT OF FEDERAL STANDARDS TO ASSURE THEIR SAFETY AND EFFECTIVENESS

Infant incubator (heating and humidifying unit) (Oxygen)

Sterilizer controls—(Pellets, strips)

Oxygen tents—(Anesthetic LO_2)

Resuscitators and related equipment (defibrillator, resuscitube)

Anesthetic equipment (including monitoring devices) (temp. EKG, Hb, etc.) oral screw, ether mask, ether hook, nasal tube, airway, tongue clamp, catheter-introducing forceps, ether dropper, mouth gag

Ultra-sound devices—therapeutic

Diathermy machine—ultra-violet, shortwave, microwave, physiotherapy equipment

Electro surgical units and accessories (cutting, coagulation, cautery, hyfrecator, conization)

Low volt generators (muscle stimulators)

Conductivity tester, operating room auto claves, skin temp. unit

Oscillograph recorders

Surgical sutures (USP)—Michel clips

Gall bladder instruments

Thoracic instruments (pacer, defibrillator)

Brain instruments (brain clips, silver foil, skull plates)

Eye instruments (tonometer)

Ear, nose and throat instruments (audiometer, tracheotomy tubes)

Genito-urinary instruments—catheter, filiform, teleprobe

OB-Gynecology instruments—pessaries

Implant materials including Teflon, Dacron, etc.

Cardiac Catheters

Metal Prosthesis—Skull plates, ear mold, orbital implant, nasolacrimal duct tubes, naso skelletal support, mandibular reconstruction, blood vessel tubes, bile duct tubes, hernia plates, testicular implants, urethral prosthesis, colostomy plugs, wire mesh, mechanical elbows, knees, etc.

EXAMPLES OF TYPES OF DEVICES WHICH THE FOOD AND DRUG ADMINISTRATION BELIEVES ARE GENERALLY RECOGNIZED AS SAFE AND EFFECTIVE AND THUS EXEMPTED FROM PREMARKET CLEARANCE OR STANDARD MAKING

Sterilizer controls—(Operating Room Tables)

Oxygen tents—(face mask) (nasal cannula) (Humidifiers) (aerosols)

Infra-red lamps—heat

Hydro therapy devices (hydro massage—paraffin)

Blood collecting equipment (vacutainer)

Bone marrow biopsy instruments

Sternal infusion equipment

Venous pressure equipment (except for transducer)

Sterilizers

Blood lancets (sterility-disposable and non-disposable)

Syringes—needles—aspirating and irrigating syringes

Anesthesia instruments (airway, masks, forceps)

Scissors (operating, bandage, suture)

Hemostatic forceps—(straight, curved, toothed, Pennington, goiter, hemorrhoid, mosquito, sponge)

Dry ice apparatus

Surgical hosiery and supports

Forceps (towel, needle holder, sponge, Allis, lap ring) splinter forceps, sterilizer forceps, tissue and intestinal forceps (Allis, Babcock, Schoenberg, Singly Williams) dressing and tissue forceps (mouse tooth, thumb, Russian, Stille Semkins). Stomach and intestinal clamp—(Ascites button, Foss; spur crushing, anastamose (Pemberton, Rankin, Clute-Fumiss, Payn, Mayo-Rabson, Scudder, Roosevelt, Doyen Stelter, De Martel Rangenstein, Von Petz)

Trocar and drainage tubes

Operating retractors (mechanical, manual)

Surgical blades and handles—(sterility) (corn chisel)

Surgical needles—needle holders—ligature coniers

Surgical sutures (USP)—Michel forceps—ring cutter—nail drill Clip applier and remover

Skin grafting equipment—fascia stripper, dermatome (Padgett-Hood, Reese, Blair, Brown)—skin planing

Gall bladder instruments (stone forceps, duct forceps, right-angle clamp, retractors, tracer, dilators, probes (rigid and flexible, duct scoops, stone spoons)

Kidney instruments (stone forceps, pedicle clamp, venil or kidney clamp)

Goiter instruments (scissors, retractors, ligature conier, forceps, tanaculun forceps)

Cardiovascular instruments (vein and artery, heart)—rachet lock, occluding forceps, vessel clamps, patent ductus clamp, needle holder, vena cava clamp, pulmonary stenosis clamp, coarctation clamp, bulldog clamp, vein strippers, vein probes, grooved directors

Thoracic instruments (pneumo-thorax apparatus, rib contractor, pneumothorax rib spreader, rib shears, rib cutters, rib guillotine, raspatory and elevator, strippers, sternum knife, lung grasping forceps, pleurectomy forceps, spirometer)

Brain instruments (dural guide, dural forceps, dural hook, nerve hook, dissector, trocar and cannula, suction tube, spatula, trephine, Gigli wire saw, Crutchfield tongs, rongeur, cranial drills, burrs

Laminectomy instruments (retractor, rongeur, dissecting scissors, punch)

Eye instruments (speculin, lacrimal probes and dilators, cataract needle, spud, geratome, chalazion curette, iris knife, cataract knife, spatula, cyrtotome, foreign body hook, strabismus hook, enucleation scissors, eyelid retractor, tenotomy scissors, irris scissors, strabismus scissors, needle holder, chalizion forceps, terephine, spheres, prisms, shields, loupe ophthalmoscope, magnet, charts

Ear, nose and throat instruments (syringe, polatizer bag, eustachian catheter, diagnostic tube, speculum, tuning fork, snare, curette, perforator, hook and spoon, ap-

plicator, rongeur, septum instrument, polypus forceps, antrum cannula, trocar, adenotome, atomizers, vaporizers, mouth gag, tonsil instruments, bronchoscope, esophagoscope, laryngoscope, bougie, tonsil hemostat, tongue depressors

Rectal instruments—anoscopes, pile clamps, cautery clamps, fistula probes, etc., crypt hook and knife, dilators, hem. needle

Genito-urinary instruments—circumcision clamp, bougue, sounds, penis clamp, cystoscopy equipment, diagnostic and therapeutic, lights, tips, snares, stone crushers, systometer

OB-Gynecology instruments—specula, retractors, dilators, sounds, curettes, membrane piercer, gauze packer, episiotomy scissors, uterine dressing forceps, tumor forceps, uterine elevator forceps, tenacula, vulsellum, hysterectomy forceps, pedicle clamps, uterine artery forceps, biopsy forceps, cytology outfit, tubal insufflation, obstetric forceps, pelvimeter, umbilical cord clamps, perineal heater, culdescope

Mechanical tourniquets

Sponge

Sponge—X-ray detectable—radio opaque

Gauze bandage—absorbent cotton, lambs wool, adhesive tape (elastoplast) bandaid—butterfly closures—lubricating jelly—stockinette—sheet wadding—cotton waste—tube gauze—elastic bandage—elastic hose—truss—abdominal and back supports—back braces—surgical soap dispenser—tube clamps and cut-offs—intravenous drip regulators—mechanical washers

Glove testing and powdering equipment

Electric bakers

Surgical clothes (conductive shoes, gowns, face masks (disposable))

Ileostomy and colostomy apparatus—intestinal tubes (Levin, Cantor, etc.)

Retractors—Hand, self-restraining

Alternating Pressure Point Unit

Beds, Cots, Cribs, (Surgical Furniture) psychiatric bed spring, restraint strap bars, eye bed, back rest, bed cradle, foot stool, safety sides, exercise bar and trapeze, portable hydraulic bed lift, irrigator rod, bassinets, scales, operating table, examining table, formula equipment, treatment table, recovery couch, stirrups, knee crutches, leg holders, armboard, safety belt, restraint straps, restraining devices, instrument table, dressing carriage, chart desks, pressure pump and suction apparatus, (nasal spray—aspiration, etc.) fume hoods, laboratory equipment (stop cocks, etc.) stretchers, wheel chairs, walkers, commodes, food supplies, Operating room lights, utensil washers, warmers, central suction, O_2 system, heating pads and vibrator (massage)

Rehabilitation equipment (tables, exercisers, parallel bars, bicycles)

Blood bank equipment (refrigerator, temperature recorder, centrifuge, pipettes)

First Aid kits

Crutches

Exemplary List of Organizations Engaged in Developing Standards for Medical Devices

Governmental:

Defense Personnel Support Center Material Standards Branch Technical Operations Division Directorate of Medical Material Attention: Major George N. Rozier 2800 South 20th Street Philadelphia, Pennsylvania 19101	(Has a great number of standards and specifications for the government of some 10,000 items of medical equipment and supplies.)
Veterans Administration Department of Medicine and Surgery Attention: Mr. Joel D. Lohr Washington, D. C.	(Has developed a number of standards and specifications for the procurement of medical devices purchased by the VA.)
Department of Commerce	(Has published a few standards and specifications for medical devices-clinical thermometers.)
National Bureau of Standards	(Has assisted in its development of standards and specifications for X-ray equipment and ultrasound heads.)

Non-Governmental:

United States Pharmacopeial Convention, Incorporated 46 Park Avenue New York, New York Attention: Arthur C. DeGraff, M.D., President	(Many Standards and Specifications are in the U.S.P.-plastics, etc.)
American Society for Tests and Materials 1916 Race Street Philadelphia, Pennsylvania 19103 Attention: Mr. T.A. Marshall, Executive Secretary	(Standards for metal alloys, working on standards for orthopedic screw and bone flats.)
American Standards Association 70 East Forty-Fifth Street New York, New York Attention: Mr. C. E. Hilton	(Developing standards for anesthesia equipment and hypodermic syringes.)